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CENTRAL FAX CENTERApplication No. 10/517,987
Amdt. dated Feb-25-2008
Reply to Office Action of Oct-13-07

MAR 1 2 2008

REMARKS/ARGUMENTS

Petition is hereby made under the provisions of 37 CFR 1.136(a) for an extension of two months of the period for response to the Office Action. Authorization to charge the fee to our deposit account is enclosed.

Applicants confirm their election of claims 19 to 54 and note that claims 1 to 18 and 55 to 64 were withdrawn from consideration. These claims now have been deleted. Such deletion is made without prejudice to the applicants right to file one or more divisional or continuation applications directed to such subject matter.

The Examiner considered that the oath and declaration was defective and required the provision of a new oath or declaration in compliance with 37 CFR 1.67(a). The Examiner indicated that the oath or declaration was defective on the basis that not every inventor had signed.

It is submitted that there is no defect in the Declarations submitted with this application. A Petition to Revive an Unintentionally Abandoned application was submitted January 16, 2006 along with a Petition under 37 CFR 1.47(a). The latter document was accompanied by, *inter alia*,

1. Declaration and Power of Attorney documents (2) signed by the inventors Brent E. Green, Radka Milanova and Kevin Segall, and
2. Declaration and Power of Attorney signed by Brent E. Green and Kevin Segall on behalf of Lei Xu.

The Petitions were considered defective on the basis that no Declaration executed by Brent E. Green and Kevin Segall on behalf of Radka Milanova had been provided.

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Applicants requested reconsideration and submitted such a Declaration. The subsequent Decision on Renewed Petition under 37 CFR 1.47(a) and 37 CFR 1.137(b) dated August 28, 2006 Granted the Petition, permitting the application to proceed forward without all the inventors signatures.

Accordingly, it is submitted that there is no new oath or declaration required.

The Examiner rejected claims 26 to 30 under 35 USC 103(a) as being unpatentable over Murray (US 6,005,076). Reconsideration is requested having regard to the following comments.

Claim 26 is directed to a process of preparing a canola protein isolate from canola oil seed meal by a series of process steps. The process steps comprise:

- extracting the canola oil seed meal to cause solubilization of the protein in the canola oil seed meal to form an aqueous protein solution having a pH about 5 to about 6.8,
- separating the aqueous protein solution from residual oil seed meal,
- increasing the protein concentration of the aqueous protein solution while maintaining the ionic strength substantially constant by effecting ultrafiltration of the aqueous protein solution to provide a concentrated protein solution,
- subjecting the concentrated protein solution to diafiltration,
- diluting the diafiltered protein solution into chilled water having a temperature below about 15°C to cause the formation of discrete protein micelles in the aqueous phase,
- settling the protein micelles to form an amorphous, sticky, gelatinous, gluten-like protein micellar mass, and

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- recovering the protein micellar mass from supernatant, the protein micellar mass having a protein content of at least about 90 wt% (N x 6.25) on a dry weight basis.

The present invention is concerned overall with producing a canola protein isolate having a reduced colour content. In the embodiment of claim 26, colour is removed by effecting diafiltration on the concentrated canola protein solution.

The Examiner discusses the disclosure of Murray in relation to claim 26 and states:

"It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use all the teaching of Murray in the entirety [entire?] document although they are not exactly in one embodiment. Since Murray yielded beneficial results in pharmaceutical industry, one of ordinary skill in the art would have been motivated to make the modifications"

The Murray et al reference has no disclosure whereby the canola protein solution resulting from extraction of the canola oil seed meal and separated from residual meal, is subjected to concentration followed by diafiltration to remove colour and phenolics. The Examiner pointed to Example 2, col. 7, wherein, in lines 46 to 48, reference is made to effecting diafiltration of the canola protein solution following by concentration, which is not the same as concentration of the canola protein solution followed by diafiltration, as recited in applicants claims. No conditions for diafiltration step are described in Example 2 of Murray et al. The Examiner's indication that Murray yielded beneficial results in the pharmaceutical industry is not understood since neither Murray nor the present invention relate to pharmaceutical products.

In order to distinguish claim 26 more clearly from the cited reference, claim 26 has been amended to incorporate the subject matter of claim 27 with respect to the manner of effecting the diafiltration. Claim 27 has been consequentially deleted and claim dependencies adjusted accordingly. It is further

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specified in amended claim 26 that the canola protein isolate is of improved colour and that the diafiltration operation is effected until no significant quantities of phenolics and visible colour are present in the permeate, as specified on page 15, paragraph 0062.

The Murray et al reference is silent as to improving the colour of the product canola protein isolate and does not specify the diafiltration conditions now specified in claim 26.

In addition, not only does Murray et al not disclose the steps of concentration of the canola protein solution followed by diafiltration using 2 to 20 volumes of diafiltration solution, the reference also fails to disclose or suggest the use of 5 to 10 volumes of diafiltration solution as specified in claim 28. Claim 29 requires that the extraction step is effected using a salt solution having a pH range of about 5 to 6.8 and that the diafiltration is effected using a diafiltration solution which is an aqueous salt solution having the same concentration and pH as the solution used in the extraction step. While Murray et al discloses that the extraction step may be effected using an aqueous salt solution having a pH in the range of about 5 to about 6.8, to the extent Murray et al discloses diafiltration, there is no disclosure or suggestion to use such solution as the diafiltration medium.

With respect to claim 30, this claim specifies that the diafiltration is effected using a membrane having a molecular weight cut-off in the range of about 3000 to about 50,000 daltons. There is no disclosure in Murray et al of any such membrane for diafiltration.

While the Murray et al reference refers to effecting a diafiltration step, a step carried out at a different stage of operation from that specified in applicants claims, there is no guidance provided by the reference as to the process conditions to be employed in such operation in the context of obtaining a canola protein isolate of improved colour, as required by applicants claims.

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Accordingly, it is submitted that claims 26 to 30, insofar as they remain in the application and in their amended form, are patentable over the applied art and hence the rejection thereof under 35 USC 103(a) as being unpatentable over Murray et al, should be withdrawn.

The Examiner rejected claims 19 to 36, 38 to 45 and 50 to 52 under 35 USC 103(a) as being unpatentable over Murray in view of Jones et al (US 4,158,656) ("Jones '656"). These claims include two independent claims, namely claims 19 and 26. Claims 26 to 30 and their relationship to the Murray reference have been discussed above. As discussed above, the Murray reference is silent as to any suggestion to effect concentration of the aqueous canola protein solution followed by diafiltration under specified conditions in a procedure to obtain a canola protein isolate of improved colour.

In this regard, the Examiner admits that:

"Murray does not teach washing the canola oil seed meal with a alcohol (ethanol), ratio of canola oil seed meal in solvent, wash till no visible colour is recovered, diafiltration solution contains an antioxidant (ascorbic) or any claimed amounts of antioxidant, membrane cut off point."

The Examiner discusses Jones '656 and its recognition of colour as a problem with canola and relies on this reference for certain teachings, considering that:

"It would have been prima facie obvious for one ordinary skill at the time the invention was made to use the antioxidant ascorbic acid in extracting process, wash rapeseeds with ethanol till no visible colour is recovered, and inactivating myrosinase in Jones et al (US 4,158,656) due to the teaching in Jones et al as mentioned above."

The features to which the Examiner refers are in subsidiary claims to claim 26. The use of antioxidant in the extracting process is recited in claim 35. Washing rapeseed itself with aqueous ethanol is not claimed but rather washing the meal with an alcohol is claimed (claim 36). The inactivation of myrosinases is

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claimed in claim 50. In any event, the Examiner does not use the Jones '656 reference to make up for the deficiencies of Murray as the primary reference with respect to claim 26.

Other features of the rejected claims not found in either Murray or Jones '656 are:

- claim 31: The diafiltration membrane of claim 30 has a molecular weight cut-off of about 500 to about 10,000 daltons
- claims 32 to 34: The diafiltration solution contains an antioxidant.
- claims 38 to 45: The supernatant from the deposition of the canola protein isolate is processed to produce a further canola protein isolate.
- claim 51: The canola oil seed meal is air-desolventized at a temperature below about 50°C to remove residual oil extraction solvent.
- claim 52: The canola oil seed meal is desolventized at an elevated temperature below about 100°C to remove residual oil extraction solvent.

Turning now to claims 19 to 25, the feature of claim 19 which distinguishes it from Murray is step (a), namely washing the oil seed meal with an alcohol. Jones '656 discloses contacting defatted seed material from, *inter alia*, rapeseed (canola), with an aqueous-lower alkanol solvent solution under substantially non-oxidizing conditions. The extraction is carried out on oil seed flour to extract contaminants and leave a concentrate. Jones '656 do not prepare a protein isolate.

In contrast, applicants use an alcohol, not an aqueous alkanol solution as in Jones '656, to extract phenolics and/or visible colour from the canola oil seed meal. To distinguish the process of claim 19 more clearly from the combined teachings of Murray and Jones '656, claim 19 has been amended to incorporate therein the subject matter of claim 20, defining the process conditions under which the washing of the meal with the alcohol is effected.

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Claim 19 also has been amended to clarify that the product is a canola protein isolate, not a "solution" as previously inadvertently specified, and that the product isolate is of decreased colour.

Having regard to the above discussion, it is submitted that the rejected claims are patentable over the applied prior art and hence that claims 19 to 36, 38 to 45 and 50 to 52, insofar as they remain in the application and in their amended form, are no longer open to rejection under 35 USC 103(a) as being unpatentable over Murray in view of Jones '656 and hence the rejection should be withdrawn.

The Examiner rejected claims 19 to 36, 38 to 45 and 50 to 54 under 35 USC 103(a) as being unpatentable over Murray in view of Jones '656 and further in view of Jones et al (US 6,146,449). The reference to the patent number of Jones et al as 6,146,449 appears to be a typographical error throughout the Office Action and that Jones et al US Patent No. 6,146,669 ("Jones '669") was intended, as listed in the Notice of References Cited.

This rejection differs from the prior one in adding claims 53 and 54 to the rejection and the Jones '669 reference. The relevance of the Murray and Jones '656 references to the patentability of claims 19 to 36, 38 to 45 and 50 to 52 has been discussed above. Claims 53 and 54 are dependent on claim 26 and are directed to effecting pasteurization of the diafiltered protein solution prior to the diluting step.

Jones '669 is directed to the preparation of a high protein nutrient from oilseed-based material. The Examiner apparently relies on this reference for a teaching that, in a process that involves the incubation of a protein-containing nutrient in a culture medium that contains oilseed-based material, it is typically advisable to pasteurize the material to ensure that microbial activity is minimized.

The procedure described in Jones '669 for the preparation of an oil seed protein product is wholly different from applicants process of preparing a

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canola protein isolate. There would appear to be nothing in the Jones '669 reference which would cause a person skilled in the art to modify the process described in the prior art to incorporate the pasteurization step claimed in claims 51 and 54.

The Examiner stated further in the Office Action that:

"Since all the inventions yielded benefits in pharmaceutical industry, one of ordinary skill in the art would have been motivated to make the modification." (emphasis added)

The reference to "pharmaceutical industry" is observed. The present invention, Murray and Jones '656 are concerned with the preparation of canola protein products useful in the food industry. The Examiner goes on to states:

"Regarding the limitation to the amount of antioxidant, and membrane cut off point, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, which is dependent on the crop and amount of insect control that is needed." (emphasis added)

The Examiner's referral to insect control is obscured. None of the present invention, Murray and Jones '656 is concerned with insect control. In the event the Examiner maintains this rejection, clarification of references to "pharmaceutical industry" and "insect control" is requested.

Accordingly, it is submitted that the rejected claims are patentable over the cited combination of prior art and hence the rejection of claims 19 to 36, 38 to 45 and 50 to 54, insofar as they remain in the application and in their amended form, under 35 USC 103(a) as being unpatentable over Murray in view of Jones '656 and Jones '669, should be withdrawn.

The Examiner rejected claims 19 to 36 and 38 to 54 under 35 USC 103(a) as being unpatentable over Murray in view of Jones '656 and Jones '669 and further in view of Diosady et al (US 6,905,713).

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This rejection differs from the prior rejection in including rejection of claims 46 to 49 and the additional reference to Diosady. The relevance of the Murray, Jones '656 and Jones '669 references to the patentability of claims 19 to 36, 38 to 45 and 50 to 54 has been discussed above. Claims 46 to 49 refer to contacting the diafiltered protein solution of claim 26 with a colour-adsorbing agent prior to the diluting step. The colour-adsorbing agent may be polyvinylpyrrolidone (claim 47).

The Diosady et al reference is concerned with the production of high quality canola protein isolates. The Examiner refers to a specific teaching that, in Example 2, col. 23, lines 10 to 15, insoluble PVP is added to treat the solution for one hour and then separated by filtration. The Examiner considered that, on the basis of that teaching:

"It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the PVP in Diosady et al, as evidenced by Field, tannic acid content can be absorbed on PVP, thus the dark brown-black pigments could be removed."

Field relates to treating waste water containing phenolic compounds and non-phenolic compounds. Field effects an initial oxidative polymerization of the phenolic compounds followed by an anaerobic purification procedure. Polyvinylpyrrolidone is used to determine the residual toxicity of the waste water following the oxidative polymerization.

In the procedure described in Diosady, in Example 2, canola oil seed meal is extracted with sodium hydroxide solution in the presence of sodium sulphite and the residual meal is separated by centrifugation and the supernatant polished using filter paper. Following addition of NaCl and SDS, the solution is reduced in volume by ultrafiltration and then the concentrated solution is diafiltered. After the diafiltration, the solution is acidified to precipitate what is termed "precipitated protein isolate" (PPI).

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The PPI is an isoelectrically precipitated product of the Diosady process, analogous to the protein micellar mass produced in applicants process and in Murray. The PVP treatment step in Diosady is applied to the solution following separation from the PPI. The PVP treatment step in Diosady is not effected prior to separation of the protein isolate but rather subsequently and would be considered to be the equivalent of the treatment of the supernatant from the protein micellar mass produced herein and in the Murray reference.

Accordingly, there is no teaching in Diosady which suggests treatment of the diafiltered concentrated canola protein solution with PVP or other colour-adsorbing agent, prior to dilution to form the protein micelles.

Accordingly, it is submitted that the rejected claims are patentable over the applied prior art and hence the rejection of claims 19 to 36 and 38 to 54, insofar as they remain in the application and in their amended form, as being unpatentable over Murray in view of Jones '656 and Jones '669 and further in view of Diosady, should be withdrawn.

The Examiner rejected claims 19 to 45 and 50 to 54 under 35 USC 103(a) as being unpatentable over Murray in view of Jones '656 and Jones '669 in view of Holbrook et al (US 6,132,795).

This rejection differs from the prior rejection of the claims based on Murray, Jones '656 and Jones '669 in including claim 37 and additionally citing Holbrook. The relevance of the combination of Murray, Jones '656 and Jones '669 to the patentability of claim 19 to 36, 38 to 45 and 50 to 54 has been discussed above and the patentability thereover established. Claim 37 recites that the protein micellar mass of claim 26 is extracted with an aqueous alcoholic solution.

The Holbrook et al reference teaches a vegetable protein composition. The Examiner points to col. 5 for a teaching that the vegetable protein concentrate

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or isolate is an alcohol extracted or washed material and to cols. 8 and 9 that the protein can be canola protein.

The Examiner conclusion is that:

"It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to extract canola protein isolate with aqueous alcoholic solution as Holbrook et al teach that alcohol extraction provides a protein material especially suitable for use in a food material."

Whatever conclusion the Examiner may reach with respect to claim 37, this claims is dependent on claim 26 which has been shown to be patentable over the basic combination of prior art. Accordingly, it is submitted that the rejected claims are patentable over the applied prior art and hence the rejection of claims 19 to 45 and 50 to 54, insofar as they remain in the application and in their amended form, under 35 USC 103(a) as being unpatentable over Murray in view of Jones '656 and Jones '669 and further in view of Holbrook, should be withdrawn.

The Examiner rejected claims 19 to 54 under 35 USC 103(a) as being unpatentable over Murray in view of Jones '656 and Jones '669 and further in view of Diosady and Holbrook et al.

This rejection differs from the preceding one in including claims 46 to 49 and further reciting the Diosady reference. The combination of Murray and Jones '656 and '669 and further in view of Holbrook with respect to claims 19 to 45 and 50 to 54 has been discussed above. The combination of Murray with Jones '656 and Jones '669 and further in view of Diosady with respect to claims 19 to 36 and 38 to 54 has been discussed above. The respective groups of claims have been demonstrated to be patentable over the respective combinations of prior art.

Accordingly, it is submitted that the rejection of claims 19 to 54 under 35 USC 103(a) as being unpatentable over Murray with Jones '656 and Jones '669 and further in view of Diosady and Holbrook, should be withdrawn.

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It is believed that this application is now in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,


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